UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,177	12/05/2001	Stephen Craig Dyar	5962-01-CA	5683

28880 7590 03/19/2003

WARNER-LAMBERT COMPANY
2800 PLYMOUTH RD
ANN ARBOR, MI 48105

EXAMINER
YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
1615	6

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,177	DYAR ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1 136(a) In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *25 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-12 and 17-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-12 and 17-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Acknowledgement of Papers: information Disclosure Statement 11/15/02 and Amendment/Response entered 10/25/02.

The Pending claims in the application are 1-7, 9-12, 17-24.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 9, 10 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The term "glassy" in claims 1,9,10, and 17 is a relative term, which renders the claim indefinite. The term "glassy" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Glassy can be taken to mean either reflective or transparent or a degree of smoothness, none of which is defined by the specification or claim. These claims do not set forth a particular meaning for the relative term. Clarification is requested.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-7, 9-12 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton (USPN 5683719) in view of Pedersen (USPN 4572833) and Bisgaier et al (USPN 5648387). The claims are drawn to a pharmaceutical dosage from comprising a central core and a surrounding diffusion limiting "sleeve". The dosage form is a co-extruded controlled release formulation. The dosage form also comprises a pharmaceutical agent such as troglitozone.

Newton teaches an extruded cylindrical core material with a covering that is somewhat permeable. The formulation of the reference comprises polyvinylpyrrolidone, PEG 4000 and disperses its active ingredient through the erosion of the central core. Newton teaches that its formulation can be introduced into capsules also. The reference also teaches that in a specific embodiment for human use, the length of the rods can be as low as 5 mm while the diameter can be as high as 8 mm. (col. 3, lin. 29 – 33, lin. 57 – 67; col. 4, lin. 28 – 50; col. 5, lin. 9 – 11, lin. 30 – 35, lin. 64 – 66; examples).

What is lacking is a teaching of the active agent and the presence of polyvinylpyrrolidone (PVP) in the exterior layer of the extrusion. With regard to the PVP Newton discloses the presence of (PVP) in the matrix of the core, it does not mention polyethylene glycol (PEG) in the matrix. Though Newton discloses PEG in the composition, it is not in the matrix, yet rather in the coating. Pedersen however, teaches that the core of its dosage form comprises PEG and PVP

(col. 5, lin. 63 – 67). Again these compound are well known in the art, and the selection of them for use in controlled-release dosage forms in well within the level of on of ordinary skill in the art.

Bisgaier provides the active agents as claimed by applicant (col. 12, lin. 42 – 53). The active agents can be combined with cellulose derivatives and is filled into capsules (examples).

With this in mind one of ordinary skill in the art would have been motivated to follow the suggestions of Newton/Pedersen as to the inclusion of antidiabetic drugs in to the formulation and substituted the troglitozone of Bisgaier in order to impart glucose affecting properties on the formulation. It would have been obvious to one of ordinary skill in the art, at the time of the invention to follow the suggestions presented in the art, to use the drug of Bisgaier with the combined formulation of Newton/Pedersen with an expected result of a less viscous co-extruded cylindrical dosage form with active agents able to increase the utilization of glucose by the body.

Allowable Subject Matter

2. Claims 17-21 and 23 appear to be free of the prior art. These claims would be in condition for allowance upon clarification of the *35 USC 112* (indefiniteness) rejections of claim 17.

Response to Arguments

3. Applicant's arguments filed 10/25/02 have been fully considered but they are not persuasive. As stated above the method claims have been deemed free of the prior art. The examine will refer to applicant argument regarding the product claims.

Applicant argues that:

a. Newton does not teach an extruded product with a "glassy" core or by the proper method.

b. The remaining references do not cure the deficiencies of Newton.

With regard to argument a., Newton teaches an extruded controlled release pharmaceutical preparation comprising a sleeve and the materials recited by applicant. Newton teaches a co-extruded controlled release pharmaceutical dosage form with an identical structure (core and surrounding diffusion layer). The material used for making the product are similar if not identical to those of applicant (PVP, polyethylene glycol, etc.). Applicant has by amendment included that the product is produced by melt extrusion. Applicant is reminded that composition claims are treated on merits of their properties and composition, not on the process by which they are produced. Burden is shifted to applicant to provided an unobvious difference between the claims product and the prior art. See *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). The products of the prior art and the present invention are used for the same purpose, and comprise the same essential elements. Also with regard to applicant's recitation to a "glassy" core produced in the invention. The examiner has above discussed how t "glassy" language renders the claims indefinite and does not impart distinctive features on the claims. The language is also merely functional language which does not impart patentability, barring clarification and a showing of unexpected results. Applicant is invited to provide how this provides a patentably distinct functional difference between the cores of the prior art and those of the invention.

With regard to argument b., the reference are applied to establish the level of skill in the art. Newton provides a co-extruded controlled release dosage form. Pederson shows the use of PVP is outer layers of pharmaceutical dosage forms. Bisgaier provides the active agents of the instant application, and under the suggestion of Newton a skilled artisan would be able to make the substitution. These references are provided not to anticipate the instant application, yet to establish the level of skill in the art, obviating the claimed invention. Applicant is reminded that prior art need not include al elements of the claimed invention, only the elements which would render the invention obvious to one of ordinary skill in the art.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young
March 18, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600